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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/557,611

11/22/2005

Atsutoshi Ikesue

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THE NATH LAW GROUP
112 South West Street
Alexandria, VA 22314

EXAMINER

WESTERBERG, NISSA M

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

06/12/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/557,611	Applicant(s) IKESUE ET AL.	
	Examiner Nissa M. Westerberg	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 - 4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 - 4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 15, 2009 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1 - 4 were rejected under 35 U.S.C. 103(a) as being unpatentable over Bertrand et al. (FR 2804024) in view of Swingle et al. (1985). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed January 15, 2009 and those set forth below.

Applicant traverses this rejection on the grounds that neither Bertrand et al. nor Swingle et al. teach or suggest the formulation recited in the instant claims. Additionally, the presently claimed pharmaceutical formulations exhibit unexpectedly superior reduction in phototoxicity through the synergistic action of the alkyl ester of gallic acid and BHT. Attention is directed towards comparisons made between these formulations and those comprising ketoprofen alone presented in the specification.

These arguments are found unpersuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking

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references individually where the rejections are based on combinations of references.

See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800

F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Bertrand et al. teaches an NSAID

concentration of 1% to 10%, with a preferred concentration ranging from 2% to 5% (p 6

of the FLS, Inc. translation, ¶ 3). The amount of antioxidant agent that supplements the

effect of the UV filters in examples 5 – 8 is approximately 0.034% w/w (BHA, p 10).

Swingle et al. discloses that BHT and propyl gallate are both antioxidants that also

possess anti-inflammatory activity and gives information regarding the potency of these

compounds and doses used in various experiments (tables 1 and 2, p 114 and 115

respectively). The amount of a specific ingredient in a composition is clearly a result

effective parameter that a person of ordinary skill in the art would routinely optimize.

Optimization of parameters is a routine practice that would be obvious for a person of

ordinary skill in the art to employ and reasonably would expect success. It would have

been customary for an artisan of ordinary skill to determine the optimal amount of each

ingredient to add in order to best achieve the desired results.

Evidence of unexpected properties may be in the form of a direct or indirect comparison of the claimed invention with the closest prior art which is commensurate in scope with the claims (MPEP 716.02(b) III). No comparison between the formulations of Bertrand et al. and those of the instant claims are presented. Additionally, the examples presented in specification make use of one concentration of ketoprofen, two concentration of BHA and one concentration of propyl gallate. The instant claims are broader, both in terms of the ingredients that may be included, and the concentrations

of those ingredients present. The concentrations provided are insufficient to establish a trend for the various amounts of the ingredients present. Therefore, this rejection is MAINTAINED.

6. Claims 1 – 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bertrand et al. (FR 2804024) in view of Williams et al. (US 6,174,540).

Bertrand et al. discloses topical formulations of non-steroidal anti-inflammatory drug which are light irradiation stable due to the presence of a UV filter, with no irritant, sensitizing and/or allergic potential (last paragraph p 3 - p 4). Ketoprofen is once such NSAID that is unstable when exposed to daylight (p 3, ¶ 3). The concentration of the NSAID can range from 1 to 10%, although 2 – 5% is preferred (p 6, ¶ 3). Antioxidants agents to supplement the effects of the UV filter such as the phenolic radical scavenger having a branched chain lower alkyl group butylated hydroxyanisole (BHA) are disclosed (p 7, ¶ 4). In the examples (p 10), the amount of BHA present is about 0.034% w/w of the formulation.

Bertrand et al. does not disclose the inclusion of alkyl ester of gallic acid such as propyl gallate in the composition.

Williams et al. discloses formulation of oil-soluble NSAIDS such as ketoprofen (abstract; col 9, ln 56 – 60). The carrier for the active ingredient can contain antioxidants such as propyl gallate, BHA and BHT (col 10, ln 26 - 29). The antioxidants are generally added to the formulation in amounts ranging from about 0.01 to about 2.0% (w/v; col 10, ln 31 – 33).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to include propyl gallate in the stabilized ketoprofen compositions taught by Bertrand et al. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because Williams et al. teaches the inclusion of an overlapping list of antioxidants in formulations with the same active ingredient, namely ketoprofen and Bertrand et al. discloses that antioxidant agents can be included in the ketoprofen formulations (p 7, ¶ 4). The amounts of ketoprofen, phenolic radical scavenger having a branched-chain lower alkyl group and propyl gallate taught by the cited prior art are encompassed by or overlay the ranges recited in the instant claims. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. **MPEP 2144.05** The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618

NMW